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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/509152

Applicant's or agent's file reference ATI-WITH		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/FI 03/00240	International filing date (day/month/year) 28.03.2003	Priority date (day/month/year) 29.03.2002	
International Patent Classification (IPC) or both national classification and IPC A61K31/4164			
Applicant ORION CORPORATION et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 27.10.2003		Date of completion of this report 28.06.2004	
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Beeck, M Telephone No. +49 89 2399-8473 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-10 as originally filed

Claims, Numbers

1-15 as originally filed

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	8-14
	No: Claims	1-7,15
Inventive step (IS)	Yes: Claims	
	No: Claims	1-15
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

2. Citations and explanations

see separate sheet

- D1: WO 01 55132 A (NOVARTIS ERFIND VERWALT GMBH ;NOVARTIS AG (CH); SEILER MAX PETER () 2 August 2001 (2001-08-02)
- D2: HELEN C. JACKSON ET AL: 'alfa-2-adrenoceptor antagonists block the stimulant effects of cocaine in mice' LIFE SCIENCES, vol. 50, no. 19, 1992, pages PL155-PL159, XP002244703
- D3: WO 97 42183 A (HOFFMANN LA ROCHE) 13 November 1997 (1997-11-13)
- D4: JUKKA SALLINEN ET AL: 'Adrenergic alfa2c-Receptors Modulate the Acoustic Startle Reflex, Prepulse Inhibition, and Aggression in Mice' THE JOURNAL OF NEUROSCIENCE, vol. 18, no. 8, 15 April 1998 (1998-04-15), pages 3035-3042, XP002244704
- D5: US-A-5 366 990 (REID LARRY D) 22 November 1994 (1994-11-22)

SECTION V:

- 1) The opinion expressed as to novelty, inventive step and industrial applicability only refers to matter for which an international search report has been drawn up.
- 2) The use of an α 2-adrenoceptor antagonist for the treatment of drug abuse is already known from document D1 (see the abstract and page 5, line 16).

Therefore the subject-matter of claims 1 to 7 and 15 is not novel (Article 33 (2) PCT).

- 3) Furthermore, document D2 describes an animal model with mice and recommends the "clinical management of cocaine addiction" with idazoxan (see the abstract and page PL-159, second paragraph).

In view of this statement it was obvious for the person skilled in the art to use idazoxan therapeutically for the treatment of cocaine abuse in humans.

Therefore the subject-matter of claim 9 does not involve an inventive step (Article 33 (3) PCT).

Also document D4 presents a mice model and states that the α 2-adrenoceptor antagonist atipamezole removes drug withdrawal symptoms induced with amphetamines or PCP (see the abstract, page 3035, right column, first paragraph,

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page 3036, left column, last but one paragraph, and page 3041, last paragraph).

In view of document D4 the subject-matter of claims 8 to 10 and 14 does not involve an inventive step either.

To use instead of atipamezole the known α 2-adrenoceptor antagonists of present claims 11 and 12, is also obvious for the person skilled in the art.

To use antidepressants, antipsychotics or anxiolytic agents in combination with the α 2-adrenoceptor antagonist appears to be obvious for the person skilled in the art as well.

Therefore the subject-matter of claims 11 to 13 does not involve an inventive step either.